K013657
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DEC 0 3 2001

BIOMET
CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy J. Bickel
(219) 267-6639

Proprietary Name: Biomet® Humeral Cable Plate

Common Name: Bone Plate

Classification Name: Bone, Fixation, Cerclage 888.3010
Plate, Fixation, Bone 888.3030

Substantially Equivalent Device: Biomet's BMP™ Cable System- K982545

Device Description: The Biomet® Humeral Cable Plate System consists of two (2) 316LVM Stainless Steel (ASTM F138) Plates.The plates are straight and have a combination of cortical screw holes and integrated cable crimp sleeves. The first plate is 156mm in length and has six (6) cable crimps and five (5) alternating cortical screw holes. The second plate is 206mm in length with eight (8) cable crimps alternating with seven (7) cortical screw holes. Both plates will utilize 3.5mm Cortical Screws and standard 2.0mm Diameter 316LVM Stainless Steel BMP™ Cable Cerclage.

Intended Use:

- Fixation of a humeral fracture near the site of an intramedullary implant.
- Fixation of fractures where a combination of screws and cerclage cables would improve stabilization.

Summary of Technologies: The Biomet® Humeral Cable Plate's material, design, sizing, and indications are similar or identical to the predicate devices.

Non-clinical Testing: Finite Analysis and literature review determined that the Biomet® Humeral Cable Plate presented no new risks and were therefore, substantially equivalent to the predicate device.

Clinical Testing: None provided as a basis for substantial equivalence.

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biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581

Re: K013657
Trade/Device Name: Biomet® Humeral Cable Plate
Regulation Number: 888.3010, 888.3030
Regulation Name: Bone fixation cerclage
Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDQ, HRS
Dated: November 5, 2001
Received: November 6, 2001

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013657
Device Name: **Biomet® Humeral Cable Plate**
Indications for Use:

- Fixation of a humeral fracture near the site of an intramedullary implant.
- Fixation of fractures where a combination of screws and cerclage cables would improve stabilization.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____
(Optional Format 1-2-96)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013657